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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MAHATAN, CHANNING

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 09/23/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/595,005

Applicant(s)

CAWSE ET AL.

Examiner

Channing S. Mahatan

Art Unit

1631

-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondenc address --**

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 34-39 and 41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 and 40 is/are rejected.
- 7) ☒ Claim(s) 2 and 25 is/are objected to.
- 8) ☒ Claim(s) 1-41 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1 Sheet. 6) ☐ Other:

DETAILED ACTION*APPLICANTS' ELECTION*

Applicants' election with traverse of Group I (Claims 1-33 and 40; drawn to a method of classification) filed 17 January 2003, in Paper No. 18, is acknowledged. Applicants traversal argument that "the subject matter of all of the claims is sufficiently related that a search of any one Group encompasses a search for the subject matter of the other Group" and "All of the claims of the present application could be examined without serious burden in view of their close relationship" is found unpersuasive. Applicants are directed to Paper No. 17, mailed 31 December 2002, which distinctly separates the different inventions based upon different modes of operation, different functions, or different effects; wherein "Group I is a method of classification utilized for the identification of different population entities, Group II is a method of preparing a chemical compound, and Group III is a system to determine and select a problem solution". Claims 34-39 and 41 are withdrawn from consideration as not directed to the elected group.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 1-33 and 40.

Claims Rejected Under 35 U.S.C. § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-33 and 40 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not

Art Unit: 1631

described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

LACK OF ENABLEMENT

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 U.S.P.Q. 546 (B.P.A.I. 1986) and reiterated by the Court of Appeals in In re Wands, 8 U.S.P.Q. 2d 1400 at 1404 (C.A.F.C. 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

Claims 1-33 and 40 are rejected under 35 U.S.C. § 112, first paragraph. It is acknowledged the claimed method executes “a genetic algorithm based on said property (catalytic) of said entities (first population of mixture entities) to identify a second population of entities.” The specification indicates “Genetic algorithms are computer programs that solve search or optimization problems by stimulating the process of evolution by natural selection” (pages 5-7, beginning on line 12 of the Specification) that these algorithms search “for favorable combinations of constraints to produce a material system that meets a specified criteria” (page 7, lines 13-14 of the Specification) and that the “second population can be used to designate a fit

Art Unit: 1631

solution” (page 11, lines 18-19 of the Specification). However, absent is the intended goal that would be achieved through the implementation of the instantly claimed method. For instance after “a second population of entities” is identified: 1) what does the information represent/mean? 2) what distinguishes the “first population of mixture entities” from the “second population of mixture entities”?; 3) what does one do with the information? 4) what criteria(s) establishes the identification of a “second population of mixture entities” as a “favorable combination” or a “fit solution/entity”(instant claim 12; and below 35 U.S.C. § 112 2nd Paragraph rejection). Thus, one skilled in the art would not understand what the information means and what to do with the information after the identification of a second population of mixture entities without an intended goal. Additionally, the above rejection corresponds to “conducting steps (A) and (B) on said second population of entities to produce a third population of entities” (instant claim 11), wherein similar questions are raised regarding the “third population of entities” as those of the “second population of entities”. No guidance, direction, or examples are provided such that one of ordinary skill in the art would have known how to use the claimed invention.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-33 and 40 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1631

VAGUE AND INDEFINITE

Claims 1, 33, and all claims dependent therefrom are indefinite due to the lack of clarity of the preamble. The preamble(s) states that it is “A method...” (claim 1) or “A high throughput method...” (claim 33) and fails to indicate an intended goal that would be achieved through the implementation of the claimed method. It is acknowledged that the final step identifies a “second population of entities”, however, absent is any indication of what the “second population of entities” represents or distinguishes it from the “first population of entities”. Clarification of the metes and bounds of the claim, via clearer claim language, is requested.

Claims 1, 4, 5, 6, 7, 8, 9, 10, 22, 26, and all claims dependent therefrom recites the phrase “a second population of entities” which is vague and indefinite. It is unclear what the “second population of entities” represents and/or distinguishes it from the “first population of entities”. Clarification of the metes and bounds of the claim, via clearer claim language, is requested.

Claim 11 recites the phrase “a third population of entities” which is vague and indefinite. It is unclear what the “third population of entities” represents and/or distinguishes it from the “first population of entities” and/or “second population of entities”. Clarification of the metes and bounds of the claim, via clearer claim language, is requested.

Claim 12 recites the phrase “a fit entity” which is vague and indefinite. The phrase implies an entity is “fit” based upon some criteria, however, such a criteria is absent from the instant claim language. Applicants can resolve this issue by particularly pointing out what criteria “a fit entity is identified” by: 1) limited to requiring some value or 2) inclusive of a random arbitrary value. In the absence of a criterion by which to identify one a “fit entity” one

Art Unit: 1631

would not know what is a “fit entity” versus a non-“fit entity”. Clarification of the metes and bounds of the claim, via clearer claim language, is requested.

Claim 13 recites the term “essentially independent” which is confusing. Is the reaction rate independent or not? If not, what limitation is implied by the phrase “essentially independent”. Applicants are requested to clarify this issue via clearer claim language.

Claim 40 is indefinite due to the lack of clarity of the claim language failing to recite a final process step, which agrees back with the preamble. The preamble states that it is “A method of selecting a carbonylation catalyst”, however, the claim recites a final step to execute a genetic algorithm based on said property of said entities to identify a second population of prospective carbonylation catalyst entities. There is no indication that a carbonylation catalyst is intended to be selected as recited in the preamble. While minor details are not required in method/process claims, at least the basic step must be recited in a positive, active fashion. The claim does not set forth the conditions/state when a carbonylation catalyst is selected. Clarification of the metes and bounds of the claim is requested via clearer claim wording.

Claims Rejected Under 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12, 14-16, and 22-28 are rejected under 35 U.S.C. § 102(b) as being anticipated by Singh et al.

Singh et al. describes a computational method of identifying and optimizing lead compounds utilizing genetic algorithms for combinatorial/chemical synthesis (Title and Abstract). The authors state the useful application of said method can be directed to high-throughput screening for the identification of new lead compounds for various molecular targets (page 1669, right column, lines 3-6). Singh et al. describes the basic ideas of the genetic algorithm (GA) method and the use as a tool for the selection and representation of chemical structures (page 1670, left column, lines 30-36). The genetic algorithm used is based on three basic strategies: selection, crossover, and mutation (page 1670, left and right columns, lines 40-42 and 1-7, respectively). The said GA paradigm employed is outlined in Scheme 2 (page 1670). Each individual of a population is represented by a bit string, which is defined as a sequence of 1's and 0's (page 1670, right column, lines 11-17). An initial set of N_{pop} individuals is formed by choosing a set of N_b -bit strings at random and each member is synthesized and evaluated for fitness, a list of pairs for mating is produced, subsequent generations are formed where each member of the first generation is ranked by fitness, the fittest individual is placed into the next generation, and the pairs of individuals are crossed-over to form the next generation (page 1670, right column, lines 23-37). Singh et al. implements and summarizes (Scheme 3) the above described method to an initial random population, synthesizes said first population (i.e. forms; refer to below definition of synthesized), determines the fitness of the first population, executes the modified genetic algorithm, repeats the method for 5 generations, and identifies active samples wherein the method would generated several generations of populations (i.e. third population) and the final generation being that which is an identified fit entity (page 1671, left and right columns, lines 18-55 and 1-46, respectively). After selection of active samples

Art Unit: 1631

fragment structures are identified by amino acid and mass spectral analyses, which utilizes reactants in liquid, as well as gas forms as required in instant claim 14 (page 1671, right column, lines 37-43; Reference 24, lines 2-17). Applicants' argument (Paper No. 10, filed 23 February 2002) was considered, wherein Applicants argued Singh et al. fails to teach or suggest "forming a first population of mixture entities and detecting a catalytic property of each of said entities". This is found unpersuasive since Singh et al. indicates mixture entities (peptides) are synthesized/formed on a solid support and catalytic properties are detected by a stromelysin assay format (fluorescence detected indicates the amount of catalytic activity by stromelysin) (Figure 2; and Scheme 3). While it is acknowledged prior to said synthesis/forming of mixture entities Singh et al. represents the initial population (i.e. first population) as bit strings Applicants instant claims encompass said bit string representation prior to synthesis/forming as presented in instant claims 4-10 wherein the bit string representation is claimed for instant claim 1, step (A). Applicants are directed to American Heritage Dictionary 2nd Edition wherein synthesized is defined as "To combine so as to form a new, complex product." Thus, Singh et al. clearly anticipate the claimed invention.

OBJECTION TO CLAIMS

Claims 2 and 25 are objected to because of a typographical error wherein the claim contains inconsistent Roman numerals: "... (i) mutation, (ii) crossover), (III) mutation and selection (iv) crossover and selection and (v) mutation, crossover and selection."

Art Unit: 1631

OBJECTION TO DISCLOSURE

The disclosure is objected to because of the following informalities:

The specification on page 14, line 1, recites "In this process, In the evaluation, each of the metal..." which is found grammatically incorrect. Applicants' are requested to correct this error.

Appropriate Correction Is Requested.

No Claims Are Allowed.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Application/Control Number: 09/595,005

Page 10

Art Unit: 1631

Date: *September 23, 2003*

Examiner Initials: *CSM*

Marianne P. Allen

MARIANNE P. ALLEN
PRIMARY EXAMINER

GROUP 1800

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